REMARKS

This Response, filed in reply to the Office Action dated January 29, 2008, is believed to be fully responsive to each point of objection and rejection raised therein. Accordingly, favorable reconsideration on the merits is respectfully requested.

Priority

On pages 2-6 of the Office Action, the Examiner appears to maintain his position that Applicants' earlier filed applications do not provide support for the genus of infectious disease, that is, *all* infectious diseases, nor for the proviso to exclude HIV infection, as presently claimed. For these reasons, the Examiner considers the effective filing date of the instant claims to be August 19, 2003, the filing date of the instant application.

Applicants have previously noted that the present application is a Divisional of pending U.S. Application No. 10/241,927, filed September 10, 2002; which is a Continuation of U.S. Application No. 09/444,027, filed November 19, 1999 (now abandoned). Applicants have also previously noted that U.S. Application No. 09/444,027, filed November 19, 1999, is a Continuation In Part of U.S. Application No. 09/154,903, filed September 17, 1998 (now abandoned); which is a Continuation In Part of U.S. Application No. 08/725,540, filed October 3, 1996 (now abandoned). For the following reasons, Applicants respectfully submit that Claims 1-23 are entitled to an effective filing date of at least October 3, 1996, the filing date of U.S. Application No. 08/725,540.

Claims 1-23 are Adequately Supported for the Treatment of *all* Infections

Applicants note that the instant claims recite (1) methods for treating a patient having an *infectious disease* by augmenting immune responses to the patient, (2) methods for increasing the number of dendritic cells in a patient having an *infectious disease*, and (3) methods for augmenting immune responses in a patient having an *infectious disease*. However, on page 5 of the Office Action, the Examiner contends that such claims are not supported by the earlier filed applications because these applications do not provide adequate written description for *all* infectious diseases. Applicants respectfully submit that the Examiner has erred in maintaining such a position.

Applicants note that a *prima facie* case of lack of written description requires a reasonable basis to challenge the adequacy of the written description, such basis equating to "a *preponderance* of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims." (Emphasis added.) See MPEP § 2163(III)(A). Applicants respectfully submit that the Examiner has failed to meet his burden in this regard, but merely supports the rejection with conclusory statements that the disclosure of bacterial and viral infection is insufficient to support the genus of "infectious disease" as claimed. To the contrary, adequate support for the instant claims is present in the specification as filed, and throughout Applicants' chain of earlier filed applications to at least U.S. Patent Application No. 08/725,540, filed October 3, 1996, for the following reasons.

First, Applicants again point to explicit written support on page 3, line 34, of U.S. Patent Application No. 08/725,540, which was filed October 3, 1996, wherein it is stated that "[t]he invention also provides a method of augmenting an immune response in a patient that has an **infectious disease** wherein the method comprises the step of administering an amount of flt3-

ligand sufficient to increase the patient's number of dendritic cells." (Emphasis added.) The same disclosure is present in each document in Applicants' chain of applications back to U.S. Patent Application No. 08/725,540. Thus, the earlier filed applications provide explicit written support for the instant claims, which recite methods for treating a patient having an *infectious disease* by augmenting immune responses to the patient, methods for increasing the number of dendritic cells in a patient having an *infectious disease*, and methods for augmenting immune responses in a patient having an *infectious disease*.

In maintaining his position, the Examiner asserts that Applicants only have support for administering the flt3-ligand to "a patient expressing bacterial or viral antigens," and that the disclosure of these species alone does not provide adequate written description for claims directed to the genus of "infectious disease." However, Applicants note that such disclosure, which occurs for example at page 11, lines 23-28, of U.S. Patent Application No. 08/725,540, and in all the documents in Applicants' chain of applications back to U.S. Patent Application No. 08/725,540, states that "[m]ore specifically, the invention provides for the use of an effective amount of flt3-ligand to increase or mobilize dendritic cells in vivo, for example, in the patient's peripheral blood or spleen. By increasing the quantity of the patient's dendritic cells, such cells may themselves be used to present antigen to T cells. *For example, the antigen may be one that already exists within the patient, such as* a tumor antigen, or a bacterial or viral antigen." (Emphasis added.) Such a disclosure provides implicit support for the genus of infectious disease as claimed. Contrary to the Examiner's position, Applicants submit that the skilled artisan would clearly understand from this disclosure that "bacterial" and "viral" diseases are recited as exemplary species of infectious disease. Further, the skilled artisan would also understand that these species are representative of the entire genus of infectious disease as

claimed, since it was well-known to the skilled artisan as of 1996 that "infectious disease" encompassed not only bacteria and viruses, but also fungi, protozoa and parasites, for example. The mere fact that Applicants have only explicitly named two representative examples does not negate a finding of adequate written description for the genus of "infectious disease," particularly when one of ordinary skill in the art would have readily envisioned the other members of the genus, as such were well-known in the art. Indeed, the Courts have repeatedly held that what is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384, 231 USPQ at 94.

Applicants note that pursuant to MPEP §2163, "[t]he [E]xaminer has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims." In other words, a rejection for lack of written description in the instant case requires a showing why one of skill in the art would *not* consider the disclosure of bacterial and viral diseases to be representative of the genus of infectious disease. Applicants respectfully submit that the Examiner has failed to provide any such showing. To the contrary, Applicants respectfully submit that the skilled artisan would understand Applicants to be in possession of the invention as claimed. Specifically, Applicants submit that one of skill in the art would understand that bacterial and viral diseases are exemplary infectious diseases of the claimed methods, in which the quantity of the patient's dendritic cells may be increased to enhance antigen presentation to T-cells, thus effecting an enhanced immune response to these diseases. However, one of skill in the art would also realize that other infectious diseases were also in the possession of Applicants, as it was well-known that the majority of other infectious agents, such as fungi, protozoa and parasites, possess the

common attribute that they express antigens recognized as foreign by the host, and that the host T-cell response directed against such foreign antigens is important for controlling such diseases. Accordingly, one of skill in the art would have understood Applicants to be in possession of the genus as claimed. Thus, it is clear that the instant specification, and the earlier filed applications, provide an explicit written description for the genus of infectious disease, in addition to disclosing two representative members of the genus.

Thus, the disclosure of the earlier filed applications satisfies the written description requirement for the genus of infectious disease.

Claims 1-23 are Adequately Supported for the Proviso to exclude HIV

The Examiner also states that the negative proviso that the infectious disease is "not HIV" is not supported in Grandparent Application No. 09/444,072. The Examiner thus contends that the instant claims are accorded an earliest effective filing date of August 19, 2003, the filing date of the instant application.

For the following reasons, Applicants respectfully traverse.

First, as previously noted by Applicants, the law does not require express disclosure in an application to support a proviso (see *In re Johnson and Farnham*, 194 U.S.P.Q. 187 (CCPA 1977)).

Nevertheless, even assuming *arguendo* that the law were to require a literal basis in the specification to support a negative proviso, which it clearly does not, Applicants respectfully submit that the proviso at issue would still be fully supported by the incorporation of U.S. Patent No. 5,554,512 into U.S. Patent Application No. 08/725,540 (see, page 4, lines 34-36).

Specifically, 37 C.F.R. § 1.57 states that incorporation by reference is accomplished by expressing a clear intent to incorporate by reference (i.e., by using the words "incorporate" and

"reference") and by clearly identifying the referenced information (i.e., a patent, application or publication). The M.P.E.P. clearly states, "an application may attempt to incorporate the content of another document or part thereof by reference to the document in the text of the specification. The information incorporated is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed." (Emphasis added.) See MPEP § 2163.07(b). Applicants expressed a clear intent to incorporate by reference the entirety of the Patent into the specification of U.S. Patent Application No. 08/725,540, as is disclosed on page 4, line 36, by recitation of "all incorporated herein by reference." Applicants also explicitly identified the referenced document by Patent No. at page 4, line 35. Thus, the incorporation by reference of U.S. Patent No. 5,554,512 into U.S. Patent Application No. 08/725,540 was proper as the requirements of 37 C.F.R. § 1.57 were met. Consistent with the law, and pursuant to MPEP § 2163.07(b), the disclosure of U.S. Patent No. 5,554,512 should be treated as part of the text of U.S. Patent Application No. 08/725,540 as filed.

Thus, Applicants again point out that explicit support for the proviso that the infectious disease is not HIV, can be found in U.S. Patent 5,554,512, which discloses that flt3-ligand may be used to treat HIV. Although on page 4 of the Office Action the Examiner contends that the proviso is not supported because Applicants rely on U.S. Patent Application No. 08/725,540 only for a description of "flt3-ligand and not for the disclosure of treating patients having infectious diseases and more particularly, not for the disclosure of treating patients having an HIV infection," such is not on point. The pertinent issue is what material was incorporated by reference into U.S. Patent Application No. 08/725,540. As noted above, Applicants satisfied the requirements of 37 C.F.R. § 1.57 to incorporate by reference the entirety of U.S. Patent

5,554,512, and there is nothing in U.S. Patent Application No. 08/725,540 to suggest that anything less than the entirety of the document was incorporated.

However, even assuming *arguendo* that the incorporation by reference of U.S. Patent 5,554,512 was interpreted, albeit improperly, to be limited to material describing the "flt3-ligand," there is nothing on page 4, lines 34-36, to even suggest that only material pertaining to the *structural* description is incorporated. Rather, such an incorporation would encompass a description of "flt3-ligand," which absent a specific indication to the contrary, would therefore include a description of properties and *uses* thereof.

Furthermore, the Examiner is invited to review *Ex parte Maziere* (Appeal No. 92-3407), in which the Board held that "[t]he Applicants of [the Maziere application] were quite correct in not further burdening the record of that file by including the text which was incorporated by reference." In *Ex parte Maziere*, the subject matter claimed in the continuation application at issue (for which incorporation was necessary) was not claimed in the parent application, however, the Board concluded that the subject matter was properly introduced into the continuation application in which the subject matter was claimed because, "to the extent that present practice would not allow incorporation by reference of 'essential matter' in a pending patent application, the Br* subject matter was not such essential material in parent Serial No. 07/072,090 since it was not claimed therein. The Applicants...were quite correct in not further burdening the record of that file by including the text which was incorporated by reference." Page 3, *Ex parte Maziere.*

Rather, the pertinent question is whether, upon incorporation of the entirety of U.S. Patent 5,554,512 into U.S. Patent Application No. 08/725,540 (which "is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of

the text of the application as filed"), an adequate written description for the treatment of HIV with flt3-ligand is present. As stated in U.S. Patent 5,554,512, "[s]ince flt3-L has been shown to stimulate T cell proliferation as well as erythrocytes (see Examples, infra), flt3-L finds use in the treatment of patients infected with the human immunodeficiency virus (HIV)." Column 7, paragraph 3. Thus, the *complete* disclosure of U.S. Patent 5,554,512, which in accordance with 37 C.F.R. § 1.57 and MPEP § 2163.07(b) includes material incorporated by reference, provides explicit written description for the treatment of HIV with flt3-ligand. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See MPEP § 2173.05.

Procedurally, the Examiner's reasoning casts serious doubt on the reliable use of the incorporation by reference expedient. In effect, although the Office sets forth in MPEP § 2163.07 that material incorporated by reference "is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed," the Examiner appears to disagree. In maintaining his position, the Examiner either believes that incorporation of the entirety of U.S. Patent 5,554,512 introduces new matter, that alternative elements positively recited in the specification may not be explicitly excluded in the claims, or that U.S. Patent 5,554,512 does not provide written support for the treatment of HIV with flt3-ligand. For the foregoing reasons, either position is improper.

Consistent with 35 U.S.C. §112, first paragraph, M.P.E.P. § 2163.07 and the holding of the Board in *Ex parte Maziere*, Applicants' incorporation by reference is proper. U.S. Patent 5,554,512 provides explicit written support for the treatment of HIV with flt3-ligand. The Office, and relevant case law, indicates that alternative elements positively recited in the specification may be explicitly excluded in the claims. See *In re Johnson*, 558 F.2d 1008, 1019,

194 USPQ 187, 196 (CCPA 1977). Thus, the proviso is proper, and instant Claims 1-23 are entitled to an earliest effective filing date of October 3, 1996.

Claims 1-23 are Adequately Described Under 35 U.S.C. § 112, First Paragraph

On page 7 of the Office Action, the Examiner maintains the rejection of Claims 1-23 under 35 U.S.C. 112, first paragraph, as lacking an adequate written description.

Specifically, the Examiner contends that the instant specification as originally filed does not provide an adequate written description for the proviso to exclude HIV.

Applicants respectfully disagree, and traverse the rejection on the following grounds.

Initially, Applicants note that on page 5, lines 9-11, of the specification as filed, U.S. Patent No. 5,554,512 is incorporated by reference therein. Thus, for the very same reasons that the proviso is supported in U.S. Patent Application No. 08/725,540, as discussed above, the proviso finds adequate written description in the specification as filed.

Withdrawal of the rejection is respectfully requested.

Claims 1-23 are Patentable Under 35 U.S.C. § 102

1. In paragraph 6, on page 8 of the Office Action, the Examiner maintains the rejection of Claims 1-23 under 35 U.S.C. § 102(e) as being anticipated by McKenna *et al.*

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

As noted above, it is Applicants' position that the earlier filed applications do support the present claims. As a result, McKenna *et al.*, which at best has a 102(e) date of November 19, 2002, is not legally effective prior art, as the present claims have an effective filing date of at least November 19, 1999.

Withdrawal of the rejection is respectfully requested.

2. In paragraph 7, on page 9 of the Office Action, the Examiner maintains the rejection of Claims 1-23 under 35 U.S.C. § 102(e) as being anticipated by Rosenthal *et al.*

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

As noted above, it is Applicants' position that the earlier filed applications do support the present claims. As a result, Rosenthal *et al.*, which at best has a 102(e) date of June 26, 2000, is not legally effective prior art, as the present claims have an effective filing date of at least November 19, 1999.

Withdrawal of the rejection is respectfully requested.

3. In paragraph 8, on page 9 of the Office Action, the Examiner maintains the rejection of Claims 1, 3-9, 11-15 and 17-23 under 35 U.S.C. § 102(e) as being anticipated by Lyman *et al.*

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

As noted above, it is Applicants' position that the earlier filed applications do support the present claims. Applicants respectfully submit that the Examiner's rejection is improper since the pending claims exclude HIV, which is specifically taught in Lyman *et al.*

It is clear that the claimed invention distinguishes over Lyman *et al.* since Lyman *et al.* do not teach or suggest treating patients afflicted with an infectious disease which is not HIV.

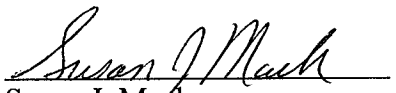
Withdrawal of the rejection is respectfully requested.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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